

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of life skills training using health literacy strategies on self-esteem and self-efficacy of female students in adolescence

Protocol summary

Study aim

The effect of life skills training based on health literacy strategies on self-esteem and self-efficacy of female students of puberty

Design

A randomized clinical trial study was conducted. At first, a district of education was selected randomly from among the education districts of Mashhad. Then two high school girls of the first grade were selected from that area. In the next step, two classes of the 7th grade students of each of the above schools were selected and finally, they were randomly assigned to a high school as a control group and the other as the test group. Sample size was determined based on the same texts and with 95% confidence and 80% test power, 35 students per group, which included 50 people per group, with a possible fall.

Settings and conduct

Two girls' high schools will be selected randomly, and 25 students from each high school in Mashhad will be randomly selected and entered into the study. At first, the test and control groups complete the self-efficacy and self-esteem questionnaires. Then the test group is trained in 5 sessions of life skills and the control group does not receive any training, immediately after training and 3 months later the questionnaires is completed by both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 7th grade student girls- Conscientious dissatisfaction with participating in the study Non-compliance criteria: Physical or mental illness- pass life skills courses

Intervention groups

In the intervention group: The educational program designed for the intervention group consisted of five sessions of theoretical education and workshops with role play and presentation in the field of self-awareness skills, effective communication, problem-solving skills and assertiveness skills based on health literacy

strategies. Is. Control group: No intervention received.

Main outcome variables

self efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160710028863N30**

Registration date: **2018-07-09, 1397/04/18**

Registration timing: **retrospective**

Last update: **2018-07-09, 1397/04/18**

Update count: **0**

Registration date

2018-07-09, 1397/04/18

Registrant information

Name

Nooshin Peyman

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 915 502 6195

Email address

peymann@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-03, 1396/12/12

Expected recruitment end date

2018-03-06, 1396/12/15

Actual recruitment start date

2018-03-03, 1396/12/12

Actual recruitment end date

2018-03-06, 1396/12/15

Trial completion date

empty

Scientific title

The effect of life skills training using health literacy strategies on self-esteem and self-efficacy of female students in adolescence

Public title

The effect of life skills training using health literacy strategies on self-esteem and self-efficacy of female students in adolescence

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

7th grade student girls Willingness to participate in the study

Exclusion criteria:

pass life skills courses Having severe physical or mental illness

Age

From **12 years** old to **14 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

A cluster sampling method is used to select an education area from among the education districts of Mashhad. Then two high school girls will be selected from that district. In the next step, two classes of the 7th grade students of each of the above schools will be selected and finally, by random method, a high school will be considered as the control group and the other will be considered as the test group. These two high schools will have a geographically spaced distance between each other so that participants can not call together.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

Street address

School of Health, Daneshgah18 Street, Daneshgah Avenue, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2018-03-03, 1396/12/12

Ethics committee reference number

IR.MUMS.REC.1396.396

Health conditions studied**1****Description of health condition studied**

Puberty

ICD-10 code

E30

ICD-10 code description

Disorders of puberty, not elsewhere classified

Primary outcomes**1****Description**

Self-efficacy level

Timepoint

Before The intervention, immediately and three months after intervention

Method of measurement

Sherer self-efficacy Questionnaire

2**Description**

self esteem level

Timepoint

Before The intervention, immediately and three months after intervention

Method of measurement

Cooper Smith self-esteem questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The training program designed for the test group consisted of 5 sessions of 90 minutes of theoretical education and workshops with role plays and demonstrations in the field of self-awareness skills, effective communication, problem-solving skills and assertiveness skills based on health literacy strategies.

Category

Lifestyle

2

Description

Control group: This group did not receive any intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

First High School Girls in Mashhad

Full name of responsible person

Nooshin Peyman

Street address

Daneshgah18, Danshgah Avenue, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3854 1514

Email

peymann@mums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Vice chancellor for research, Mashhad University of Medical Sciences, In front of Daneshgah18, Danshgah Avenue, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3854 1514

Email

tafaghodim@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Nooshin Peyman

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

School of Health, Daneshgah18 Street, Danshgah Avenue, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3854 1514

Email

peymann@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Nooshin Peyman

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Daneshgah18, Danshgah Avenue, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3854 1514

Email

peymann@mums.ac.ir

Phone

+98 51 3854 1514

Email

peymann@mums.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Potential data is sharable after distinguishing people

When the data will become available and for how long

Start the access period one month after the publication of result

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

Data is sent through an official request and by email

From where data/document is obtainable

Dr Nooshin Peyman Peymann@mums.ac.ir

What processes are involved for a request to access data/document

Data is sent through an official request and by email

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Nooshin Peyman

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Daneshgah18, Danshgah Avenue, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944